HPI-35 4/10/98

DEPARTMENT OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG ADMINISTRATION
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New Orleans, LA 70122-3896
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June 3, 1998

WARNING LETTER NO. 98-NOL-23

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mrs. Annabelle R. Alleman, Co-Owner
Alleman Seafood
1918 Highway 70
Pierre Part, Louisiana 70339

Dear Mrs. Alleman:

During an inspection of Alleman Seafood, Pierre Part, Louisiana, conducted on April 30 – May 1, 1998, our investigators documented numerous insanitary conditions in your peeled crawfish tail meat operation. This causes your finished product, crawfish tail meat, to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug and Cosmetic Act.

Objectionable insanitary conditions noted included:

1) Employees routinely handling live crawfish and then cooked crawfish without washing and sanitizing their hands;

2) Employee routinely handling dirty encrusted objects and then handling cooked crawfish without washing and sanitizing his hands;

3) Employee handling objects from the dirty wet cooler room floor, then handling cooked crawfish without washing and sanitizing his hands;

4) Employees routinely contacting insanitary objects including noses/faces, dirty encrusted doors/equipment, telephone, eyeglasses, hat/clothing, and coughing into their hands, and then contacting cooked crawfish during cooking and peeling without washing and sanitizing their hands;

5) Employees routinely wore their aprons to restrooms, or while on breaks, then resumed peeling without washing and sanitizing their aprons;

6) Two peelers with gray masking tape and one peeler with a adhesive strip bandage on their fingers while peeling crawfish;

7) Three peelers allowing clothing to directly contact cooked crawfish on the peeling table;

8) Ten live flies in the break room during operations and one live fly on packing equipment in the packing room;

9) Inadequate hand sanitizers; and,

10) Dirty encrusted food contact equipment.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure adherence with each requirement of the Good Manufacturing Practice Regulations.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. This may include seizure and/or injunction.

You should notify this office in writing, within 15 working days of receipt of this letter, of the steps taken to correct the noted violations, including an explanation of each step taken to prevent the recurrence of similar violations. If corrective action can not be completed within 15 working days, state the reason for this delay and the time within which the corrections will be completed.

Your response should be directed to Richard D. Debo, Compliance Officer, U.S. Food and Drug Administration, 4298 Elysian Fields Avenue, New Orleans, Louisiana, 70122-3896, telephone number (504) 589-7166. Should you have any questions concerning the contents of this letter, or if you desire a meeting with the agency staff, do not hesitate to contact Mr. Debo.

Additionally, this inspection was conducted to determine compliance with FDA's seafood processing regulations (21 CFR 123) and the Good Manufacturing Practices requirements for foods (21 CFR 110).

The seafood processing regulations, which became effective on December 18, 1997, require you to implement a preventive system of food safety controls known as Hazard Analysis Critical Control Point (HACCP). HACCP essentially involves: (1) identifying food safety hazards that, in the absence of controls, are reasonably likely to occur in your products; and (2) having controls at "critical control points" in the processing operations to eliminate or minimize the likelihood the identified hazards will occur. These are the kinds of measures prudent processors already take. HACCP provides a systematic way of taking those measures that demonstrates to us, to your customers, and to consumers, that you are routinely practicing food safety by design. Seafood processors that have fully operating HACCP systems advise us that they benefit from it

in several ways, including having a more safety oriented workforce, having less product waste, and having fewer problems generally.

During the inspection, the FDA investigator observed shortcomings in your system that, upon preliminary review, appear to be deviations from the principles of HACCP and the significant requirements of the program. The FDA investigator also provided you with a copy of the Domestic Seafood HACCP Report (form FDA-3501) and the FDA-483 which presents his/her evaluation of your firm's performance regarding various aspects of the HACCP and GMP requirements. The observations of concern to us are as follows:

1) Failure to have and implement a HACCP Plan as required under Title 21, Code of Federal Regulations, (CFR) Part 123.6(b); and,

2) Failure to maintain sanitation monitoring records as required by 21 CFR part 123.11.

Also, it is not apparent how you are controlling the food safety hazard associated with the formation of toxin by C. botulinum, for the refrigerated vacuum packaged Fresh Peeled Crawfish Tail Meat after processing. Unless this product is maintained in a frozen condition until immediately before use by the customer or that the boiling step destroys both the vegetative and spore states of C. botulinum, the only control to prevent toxin production by C. botulinum in this product is storage below 38° F, which requires constant monitoring of refrigeration during processor storage, distribution and at the wholesale and retail level.

Objectionable equipment and insanitary conditions as listed on Form FDA-483 and Form FDA-3501 are an indication that sanitation monitoring [21 CFR 123.11(b)] at your firm is inadequate. Calling your attention to the objectionable insanitary conditions is in the interest of having your firm improve its sanitation program consistent with HACCP principles. A failure to make appropriate corrections could cause your HACCP processing system to be found unacceptable during a future FDA inspection. The noted objectionable insanitary conditions are noted in the body of this letter and on the attached FDA-483.

We encourage you to make the necessary improvements as soon as possible. However, if you disagree with FDA's preliminary assessment of deviations from HACCP Regulations, you should explain how your system identifies hazards and implements controls in a manner the agency should regard as complying with the regulations. We understand that HACCP systems may be uniquely tailored to meet the circumstances of the individual processor and there may be more than one right way to control hazards.

In either case, it is essential that you respond to this office on this matter within 30 working days of the receipt of this letter. Upon receipt of a timely response, we will work with you to resolve any outstanding issues associated with your HACCP system. If we do not hear from you, or if your response is inadequate, we will assume our preliminary conclusions are correct and we will schedule a follow-up inspection for the immediate future.

Your reply, relating to these concerns, should be directed to the Food and Drug Administration, Attention: **Richard D. Debo, 4298 Elysian Fields Avenue, New Orleans, Louisiana 70122-3896.** If you have questions regarding the implementation of the HACCP regulation or the application of HACCP to your specific process, you may contact Mr. Debo at (504) 589-7166 for answers and/or direction towards guidance and sources of training in achieving compliance.

Sincerely,

James E. Gamet
District Director
New Orleans District Office

Enclosure: FDA-483

/tjt